



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0262]

Withdrawal of Approval of Part of a New Animal Drug Application; Tiamulin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of those parts of a new animal drug application (NADA) for a tiamulin Type A medicated article that pertain to the production indications for use of increased rate of weight gain and improved feed efficiency in swine. This action is being taken at the sponsor's request because this product is no longer marketed for these uses.

DATES: Withdrawal of approval is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc. (Novartis), 3200

Northline Ave., suite 300, Greensboro, NC 27408, has requested that FDA withdraw approval of those parts of NADA 139-472 for DENAGARD (tiamulin) Type A medicated article pertaining to the production indications for use of increased rate of weight gain and improved feed efficiency in swine. Novartis requested voluntary withdrawal of approval of these indications for use because this product is no longer marketed for these uses. Revised product labeling reflecting the withdrawal of these indications has been approved in a supplement to NADA 139-472.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of those parts of NADA 139-472 pertaining to the production indications for use of increased rate of weight gain and improved feed efficiency in swine are hereby withdrawn, effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the withdrawal of approval of those parts of NADA 139-472.

Dated: March 21, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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